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109TH CONGRESS
2D SESSION

H. R. 5641

To promote safe and ethical clinical trials of drugs and other test articles on people overseas.

IN THE HOUSE OF REPRESENTATIVES

JUNE 20, 2006

Mr. LANTOS (for himself and Mr. BROWN of Ohio) introduced the following bill; which was referred to the Committee on International Relations

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A BILL

To promote safe and ethical clinical trials of drugs and other test articles on people overseas.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe Overseas Human Testing Act''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Before a manufacturer of a new drug or device can market its new product, the Food and Drug Administration (in this section referred to as the

''FDA'') requires that the manufacturer conduct laboratory and clinical trials to ascertain the product's safety and effectiveness.

(2) Federal regulations mandate that an Institutional Review Board (IRB), which is comprised of scientists, physicians, and lay people, review the protocol or research plan and the informed consent form of the proposed clinical trial to ensure, among other things, that the health and safety of the human participants are not unnecessarily endangered.

(3) Institutional Review Boards also verify that the manufacturer's clinical researchers implement appropriate additional safeguards to protect the rights and welfare of potentially vulnerable populations and persons who are economically or educationally disadvantaged.

(4) Most importantly, the IRBs help assure the FDA that manufacturers of new drugs and medical devices adequately inform human participants of the anticipated risks and the likelihood of projected benefits derived from their participation in the clinical trials, and then secure the voluntary consent of the participants.

(5) For the purpose of supporting the safety and efficacy of the test article, the FDA, however, may accept the results of clinical trials with human participants which are conducted outside of the United States and do not meet United States IRB and ethical requirements.

(6) Foreign clinical trials involving human participants only need to conform to either international norms on clinical investigations or the laws and regulations of the country in which the research is to be conducted. However, neither international nor most host-country standards meet the stringent requirements of the United States.

(7) International and most foreign-country legal protections do not adequately shield participants in clinical investigations of a new drug or device from unethical, dangerous, or unscrupulous research practices.

(8) Some researchers exploit the fragile regulatory systems, high illiteracy rates, and public health failures of developing countries to test their experimental drugs and devices on misinformed and unwilling human participants.

(9) On April 30, 2001, the National Bioethics Advisory Commission (NBAC) presented to the

President a report, entitled ''Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries'', which discussed the ethical issues generated by research on human participants in developing countries and recommended ways to help ensure the health and safety of these human participants. The NBAC highlighted the inadequate regulatory protections which are afforded to human participants in many clinical trials abroad.

(10) In September 2001, the Office of the Inspector General of the Department of Health and Human Services released the report entitled ''The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects''. In the report, the Inspector General acknowledged that key entities which oversee or study foreign research, including United States regulatory agencies and the World Health Organization, have raised concerns about the lack of experience and insufficient monitoring practices of many foreign IRBs.

(11) The Inspector General also recommended, among other things, that the FDA collect more information on the performance of foreign IRBs and the growth and location of foreign clinical investigations.

(12) While Federal regulation should accelerate, whenever possible, the delivery from laboratory to patients of new drugs which are designed to treat devastating illnesses, existing law permits manufacturers to profit from the misery and pain of uniformed, misinformed, and unwilling patients in developing countries.

(13) On June 10, 2004, the FDA issued a proposed rule that would, among other things, replace the existing requirement that foreign clinical studies be conducted in accordance with the ethical principles which are contained in the Declaration of Helsinki (described in section 312.120(c) of title 21, Code of Federal Regulations), with a requirement that such studies comply with good clinical practice (GCP).

(14) Although pharmaceutical and biotechnology companies and their lobbyists, in submitted public comment, generally support the proposed rule, other organizations, such as the AIDS Vaccine Advocacy Coalition and Public Citizen, have objected to the proposed deletion of the Declaration of Helsinki from applicable regulations because the removal may result in the use of placebos or other drugs which are less effective than established treat-

ments in control groups facing life-threatening medical conditions.

(15) As of June 15, 2006, the FDA has not promulgated a final version of the June 2004 proposed rule.

SEC. 3. STATEMENT OF POLICY.

It is the policy of the United States to control the export of test articles which are intended for clinical investigations involving human participants in order to—

(1) foster public health and safety;

(2) prevent injury to the foreign policy of the United States; and

(3) preserve the credibility of the United States as a responsible trading partner.

SEC. 4. MEASURES TO PROTECT THE PUBLIC HEALTH.

(a) IN GENERAL.—In order to carry out the policy set forth in section 3, test articles intended for clinical investigations may be exported only pursuant to an export license approved by the President. The President may exercise the authorities of the Export Administration Act of 1979, as continued in effect pursuant to the International Emergency Economic Powers Act, to carry out this section.

(b) CRITERIA FOR EXPORT LICENSE.—In addition to any other requirements that may apply, including under

the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and regulations issued under either such Act, the President shall require, as a prerequisite for approval of an export license for a test article required by subsection (a) of this section, that an applicant for such license—

(1) identify each clinical investigation for which the test article is intended;

(2) secure a certification from an institutional review board that each of the protocols for every clinical investigation identified under paragraph (1) has been reviewed by the institutional review board and has, at a minimum, met substantially the same standards for the protection of the rights and welfare of human subjects as the standards that would be required for IRB approval of the protocol if the protocol were for a clinical investigation of the test article pursuant to the Federal Food, Drug, and Cosmetic Act ; and

(3) submit the certification secured under paragraph (2) to the President.

(c) REPORTING REQUIREMENT.—Not later than one year after the date of the enactment of this Act, and annually thereafter, the President shall prepare and submit to the appropriate congressional committees a report regard-

ing the approval of export licenses required by subsection (a). Such report shall include—

(1) the names of the applicants for such export licenses;

(2) the names of approved applicants for such export licenses; and

(3) the destination country or countries for each application for such export licenses.

(d) DEFINITIONS.—In this section:

(1) APPLICATION FOR RESEARCH OR MARKETING PERMIT.—The term ''application for research or marketing permit'' has the meaning given that term in section 56.102(b) of title 21, Code of Federal Regulations, or successor regulations.

(2) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ''appropriate congressional committees'' means the Committee on International Relations of the House of Representatives and the Committee on Banking, Housing, and Urban Affairs of the Senate.

(3) CLINICAL INVESTIGATION.—

(A) IN GENERAL.—The term ''clinical investigation'' means any experiment that—

(i) involves a test article and one or more human subjects; and

(ii)(I) the results of which are intended to be later submitted to, or held for inspection by, the Secretary of Health and Human Services as part of an application for research or marketing permit; or

(II) must meet the requirements for prior submission to such Secretary under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360j(g)).

(B) EXCLUSION.—The term ''clinical investigation'' does not include experiments that must meet the requirements of part 58 of title 21, Code of Federal Regulations, or successor regulations, regarding nonclinical laboratory studies.

(4) DESTINATION COUNTRY.—The term ''destination country'' means the country into which test articles are being exported.

(5) HUMAN SUBJECT.—The term ''human subject'' means an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy individual or a patient.

(6) INSTITUTION.—The term ''institution'' means any public or private entity or agency (including Federal, State, and other agencies), either in the United States or other country.

(7) INSTITUTIONAL REVIEW BOARD; IRB.—The terms ''institutional review board'' and ''IRB'' mean any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

(8) IRB APPROVAL.—The term ''IRB approval'' means the determination of an IRB made pursuant to part 56 of title 21, Code of Federal Regulations, or successor regulations, that a clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(9) TEST ARTICLE.—The term ''test article'' means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article that would be subject to

regulation under the Federal Food, Drug, and Cosmetic Act if introduced into interstate commerce.

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